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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,214	12/26/2001	Dan L. Eaton	P3030R1C11	6102

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EXAMINER	
KOLKER, DANIEL E	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	10/036,214	Applicant(s) EATON ET AL.	
	Examiner Daniel Kolker	Art Unit 1649	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27 – 29, 32 – 34, and 38 – 51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *27 – 29, 32 – 34, and 38 – 41* is/are allowed.

6)☒ Claim(s) *42-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/28/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649.

2. Applicant's remarks, amendments, and declaration filed 28 June 2005 have been entered in full. Applicant has cancelled claims 22 – 26, 30 – 31, and 35 – 37 and added new claims 42 – 51. Claims 27 – 29, 32 – 34, and 38 – 51 are pending.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The correction of inventorship under 37 CFR § 1.48(b) is accepted.

Information Disclosure Statement

5. The information disclosure statement filed 28 June 2005 has been considered. The BLAST results indicate that applicants are aware of nucleic acids and proteins with identity or homology to the one claimed herein. However the results cannot be considered because there is no alignment provided, nor is there an indication of the percent identity between the claimed sequence and the reference sequences. Applicant states on pp. 6 - 7 of the remarks that the newly-submitted documents include references to specific accession numbers and sequences. Applicant is advised that the BLAST results submitted appear to be a list of sequences which match, but do not provide either alignments or indications of how the sequences are related to the instantly-claimed peptides. Therefore the examiner cannot determine if the sequence accession numbers submitted by applicant constitute prior art. Furthermore the search results submitted appear to be the results are not publicly available documents. Applicant is directed to MPEP 609 and 37 CFR 1.97 and 1.98.

Withdrawn Objections and Rejections

6. The following objections or rejections made in the previous office action are withdrawn:

The objections to the specification. Applicant has deleted the hyperlinks and changed the title.

The rejections of claims 27 and 38 – 41 under 35 USC 112 first paragraph for not being fully enabled over their scope and for not being fully described. Applicant has amended claim

27 to delete the language which was considered non-enabled and not described, and changed the dependency of claims 38-41.

The rejections of claims 27 – 29 and 32 – 34 under 35 USC 112 for failing to comply with the enablement requirement, as far as it relates to deposit of biological material. Applicant's declaration filed 28 June 2005 is sufficient to overcome the rejection.

The rejections under 35 USC 112, second paragraph. Applicant has amended the claims to delete confusing language relating to the extracellular domain and has cancelled claims drawn to hybridization.

The rejections under 35 USC 102. Applicant has cancelled claims drawn to nucleic acids less than 80 – 95% identical to SEQ ID NO:60 and claims drawn to nucleic acids which hybridize to a sequence, rendering the rejections moot.

Maintained Objections and Rejections

Priority

7. The effective priority date of the instant application is considered to be the filing date of the international application PCT/US00/05601, filed 1 March 2000 for the reasons made of record in the previous office action. Applicant did not traverse this statement.

Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 112

8. Claims 42 – 51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids which encode polypeptides at least 98% identical to SEQ ID NO:61 which induce fetal hemoglobin, does not reasonably provide enablement for for nucleic acids which encode polypeptides at least 98% identical to SEQ ID NO:61 which induce mesangial cell proliferation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification discloses, on pp. 168 – 169, the results of an experiment in which PRO4408 was able to induce mesangial cell proliferation. However, the threshold used in determining whether a particular PRO molecule counts as "positive" in this assay would not be considered reasonable by one of skill in the art. The specification discloses (p. 169, lines 1 – 2) that positives in this assay include anything which is at least 15% over the control reading. The

post-filing publication by Rovin et al. (2002. Kidney International 61:1293-1302, cited by applicant on the IDS filed 28 June 2005) indicates that a 21% increase in human mesangial cell proliferation is not statistically significant (see particularly p. 1296, lines 3 – 6). Note that the assay used by Rovin et al. is similar to that disclosed in Example 41: both used the Cell-Titer 96 reagent from Promega, measured absorbance at 490 nm, and expressed the results as the ratio of the absorbance for a given treatment to that of control cells (see Specification, p. 168 – 169, and Rovin et al., p. 1294, second column, second complete paragraph). Because the specification does not disclose the degree to which PRO4408 increased cell proliferation, or whether or not the results were statistically significant, a skilled artisan would not conclude that PRO4408 is able to induce proliferation of kidney mesangial cells. The teachings of Rovin indicate that the threshold used by applicant is too low and thus the artisan would not be able to make nucleic acids which encode a polypeptide less than 100% identical to SEQ ID NO:61 that induce proliferation, as even the peptide of SEQ ID NO:61 does not induce proliferation to the art-accepted standard.

9. Claims 42 – 51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to polynucleotides at least 99% identical to SEQ ID NO:60 (claim 48) or to polynucleotides that encode polypeptides at least 98% (claim 42) or 99% (claim 43) identical to SEQ ID NO:61, wherein the polypeptides have certain properties recited in the claim. While the specification contemplates variants of the nucleic acid and protein sequences, there only a disclosure of a single member of the genus of claimed nucleic acids, namely SEQ ID NO:60. Neither the specification nor the art indicates to the artisan which regions of the claimed nucleic acid must be conserved, or which regions can be changed without affecting function.

Applicant is directed to the Revised Written Description Interim Guidelines Training Materials, available on the internet at http://www.uspto.gov/web/offices/pac/writtendesc.pdf, particularly the flow chart on page 9 which is analogous to the instant situation. Independent claims 42, 43, and 48 are genus claims, but neither the art nor the specification discloses a representative number of species falling within the genus. There is not even identification of

any particular portion of the structure at either the nucleic acid or amino acid level that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF'S were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, nucleic acids comprising the sequence set forth in SEQ ID NO:60 or encoding the protein of SEQ ID NO:61, but not the full breadth of the claims meet the written description provision of 35 U.S.C. § 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Conclusion

10. Claims 27 – 29, 32 – 34, and 38 – 41 are allowed.

11. Claims 42 – 51 are rejected.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel E. Kolker, Ph.D.
August 19, 2005

JANET ANDRES
SUPERVISORY PATENT EXAMINER